



EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of a health claim related to Cynatine® and maintenance of normal joint mobility pursuant to Article 13(5) of Regulation (EC) No 1924/2006

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SCIENTIFIC OPINION

Scientific Opinion on the substantiation of a health claim related to Cynatine[®] and maintenance of normal joint mobility pursuant to Article 13(5) of Regulation (EC) No 1924/2006¹

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)^{2, 3}

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

Following an application from Roxlor Nutra LLC, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of Belgium, the Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on the scientific substantiation of a health claim related to Cynatine[®] and maintenance of normal joint mobility. The Panel considers that Cynatine[®], which is a keratin powder extracted from sheep wool, is sufficiently characterised. The claimed effect proposed by the applicant refers to “joint flexibility”. The Panel considers that maintenance of normal joint mobility is a beneficial physiological effect. The applicant presented one unpublished human intervention study as being pertinent to the health claim. The Panel notes that the study was specifically designed to identify patients with clinical diagnosis of osteoarthritis, and considers that normal cells and tissues are genetically (gene expression) and functionally different from osteoarthritic cells and tissues, and therefore may respond differently to interventions with exogenous substances. In addition, the mechanisms involved in the onset and/or progression of osteoarthritis are largely unknown. It would have to be established, therefore, that an intervention which has an effect on the progression of the disease (in patients with osteoarthritis) would also have an effect on its onset (subjects without the disease). The Panel considers that no conclusions can be drawn from this study for the scientific substantiation of the claim. The Panel concludes that a cause and effect relationship has not been established between the consumption of Cynatine[®] and maintenance of normal joint mobility.

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KEY WORDS

Cynatine[®], joints, mobility, osteoarthritis, chronic inflammation, health claims

¹ On request from the Competent Authority of Belgium following an application by Roxlor Nutra LLC, Question No EFSA-Q-2012-00570, adopted on 28 November 2012.

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SUMMARY

Following an application from Roxlor Nutra LLC, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of Belgium, the Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on the scientific substantiation of a health claim related to Cynatine® and maintenance of normal joint mobility.

The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence and including a request for the protection of proprietary data.

The food that is the subject of the health claim is Cynatine®, which is a keratin powder extracted from sheep wool. The Panel considers that Cynatine® is sufficiently characterised.

The claimed effect proposed by the applicant refers to “joint flexibility”. The target population proposed by the applicant is healthy adults, and in particular healthy individuals with “sensitive joints”. The Panel considers that the health claim refers to the maintenance of joint mobility in subjects without chronic joint diseases, and does not include the treatment of chronic joint diseases. The Panel considers that maintenance of normal joint mobility is a beneficial physiological effect.

The applicant presented one unpublished human intervention study as being pertinent to the health claim.

The study was a randomised, double-blind, placebo-controlled parallel trial in which 50 subjects with clinical diagnosis of osteoarthritis of the knee were randomised to consume daily 500 mg of Cynatine FLX™ or placebo for 60 days. Inclusion criteria were 25-75 years of age, unilateral or bilateral osteoarthritis of the knee according to the American College of Rheumatology clinical criteria for the classification of idiopathic osteoarthritis of the knee, a total Western Ontario and McMaster Universities (WOMAC) osteoarthritis score of 15-75 (the worst score being 96) in the target knee, and ability to walk unassisted.

The Panel notes that the study was specifically designed to identify patients with clinical diagnosis of osteoarthritis, and considers that normal cells and tissues are genetically (gene expression) and functionally different from osteoarthritic cells and tissues, and therefore may respond differently to interventions with exogenous substances. In addition, the mechanisms involved in the onset and/or progression of osteoarthritis are largely unknown. It would have to be established, therefore, that an intervention which has an effect on the progression of the disease (in patients with osteoarthritis) would also have an effect on its onset (subjects without the disease). The Panel considers that no conclusions can be drawn from this study for the scientific substantiation of the claim.

The Panel notes that no studies from which conclusions could be drawn for the scientific substantiation of the claim were provided by the applicant.

The Panel concludes that a cause and effect relationship has not been established between the consumption of Cynatine® and maintenance of normal joint mobility.

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BACKGROUND

Regulation (EC) No 1924/2006⁴ harmonises the provisions that relate to nutrition and health claims, and establishes rules governing the Community authorisation of health claims made on foods. As a rule, health claims are prohibited unless they comply with the general and specific requirements of this Regulation, are authorised in accordance with this Regulation, and are included in the lists of authorised claims provided for in Articles 13 and 14 thereof. In particular, Article 13(5) of this Regulation lays down provisions for the addition of claims (other than those referring to the reduction of disease risk and to children's development and health) which are based on newly developed scientific evidence, or which include a request for the protection of proprietary data, to the Community list of permitted claims referred to in Article 13(3).

According to Article 18 of this Regulation, an application for inclusion in the Community list of permitted claims referred to in Article 13(3) shall be submitted by the applicant to the national competent authority of a Member State, which will make the application and any supplementary information supplied by the applicant available to the European Food Safety Authority (EFSA).

STEPS TAKEN BY EFSA

- The application was received on 04/05/2012.
- The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence and including a request for the protection of proprietary data.
- On 31/05/2012, during the validation process of the application, EFSA sent a request to the applicant to provide missing information.
- The applicant provided the missing information on 10/07/2012.
- The scientific evaluation procedure started on 17/07/2012.
- On 26/10/2012, the Working Group on Claims of the NDA Panel agreed on a list of questions for the applicant to provide additional information to accompany the application, and the clock was stopped on 01/11/2012, in compliance with Article 18(3) of Regulation (EC) No 1924/2006.
- On 07/11/2012, EFSA received the requested information as submitted by the applicant and the clock was restarted, in compliance with Article 18(3) of Regulation (EC) No 1924/2006.
- During its meeting on 28/11/2012, the NDA Panel, having evaluated the data submitted, adopted an opinion on the scientific substantiation of a health claim related to Cynatine® and maintenance of normal joint mobility.

TERMS OF REFERENCE

EFSA is requested to evaluate the scientific data submitted by the applicant in accordance with Article 16(3) of Regulation (EC) No 1924/2006. On the basis of that evaluation, EFSA will issue an opinion on the scientific substantiation of a health claim related to: Cynatine® and maintenance of normal joint mobility.

EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation for the marketing of Cynatine®, a positive assessment of its safety, nor a decision on whether Cynatine® is, or

⁴ Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. OJ L 404, 30.12.2006, p. 9–25.

is not, classified as a foodstuff. It should be noted that such an assessment is not foreseen in the framework of Regulation (EC) No 1924/2006.

It should also be highlighted that the scope, the proposed wording of the claim, and the conditions of use as proposed by the applicant may be subject to changes, pending the outcome of the authorisation procedure foreseen in Article 18(4) of Regulation (EC) No 1924/2006.

INFORMATION PROVIDED BY THE APPLICANT

Applicant's name and address: Roxlor Nutra LLC, 1013 Centre Rd. Suite 106, Wilmington, DE-USA 19805.

The application includes a request for the protection of proprietary data for one unpublished study (Wilson and Veghte, 2010), in accordance with Article 21 of Regulation (EC) No 1924/2006.

Food/constituent as stated by the applicant

According to the applicant, Cynatine®, which is a keratin powder extracted from sheep wool.

Health relationship as claimed by the applicant

According to the applicant, the health claim refers to the support of joint flexibility.

Wording of the health claim as proposed by the applicant

The applicant has proposed the following wording for the health claim: “daily consumption of 500 mg of Cynatine® helps to support joint flexibility”.

The following alternative wording was proposed: “helps support joint function by reducing pain and stiffness”.

Specific conditions of use as proposed by the applicant

The applicant has proposed an intake of 500 mg/day of Cynatine® for 60 consecutive days, to be consumed with a large glass of plain water. The target population is healthy adults, and in particular healthy individuals with “sensitive joints”.

ASSESSMENT

1. Characterisation of the food/constituent

The food that is the subject of the health claim is Cynatine®, which is a keratin powder extracted from sheep wool.

Cynatine® contains on average 72 g protein, 25.8 g ash and 2.2 g moisture per 100 g of the commercial product. The protein is extracted from New Zealand sheep wool and subsequently enzymatically hydrolysed into peptides, following a patented manufacturing process (WO 03/011894 A1). Information on the typical amino acid profile and size distribution of the peptides, as well as information on the manufacturing process, batch to batch variability, stability and microbiological analysis was provided.

The Panel considers that the food, Cynatine®, which is the subject of the health claim, is sufficiently characterised.

2. Relevance of the claimed effect to human health

The claimed effect proposed by the applicant refers to “joint flexibility”. The target population proposed by the applicant is healthy adults, and in particular healthy individuals with “sensitive joints”. “Sensitive joints” was defined by the applicant as joints “in which some level of discomfort

(pain, stiffness or otherwise) is felt, but it is not to the point where the discomfort is debilitating or requires the use of medication”. The applicant also clarified that “it would not include any individuals who have been diagnosed as having any specific joint disease which would define them as unhealthy individuals”.

The Panel considers that the health claim refers to the maintenance of joint mobility in subjects without chronic joint diseases, and does not include the treatment of chronic joint diseases.

The Panel considers that maintenance of normal joint mobility is a beneficial physiological effect.

3. Scientific substantiation of the claimed effect

The applicant performed a literature search in PubMed, ScienceDirect, Google, Google Scholar, IBIDS, Scopus and Scirus using the search terms [(“Cynatine®”) AND (“osteoarthritis” OR “joint” OR “rheumatoid arthritis”)] to identify studies conducted with at least 500 mg/day of Cynatine®. No published studies were found. The Panel notes the limited scope of the literature search performed.

The applicant presented one unpublished human intervention study as being pertinent to the health claim (Wilson and Veghte, 2010, unpublished, claimed as proprietary by the applicant).

The study (Wilson and Veghte, 2010, unpublished) was a randomised, double-blind, placebo-controlled parallel trial in which 50 subjects with clinical diagnosis of osteoarthritis (OA) of the knee were randomised to consume daily 500 mg of Cynatine FLX™ (n=25, 18 females, 52.6±10.0 years) or placebo (maltodextrin; n=25, 14 females, 52.3±9.5 years) for 60 days. Inclusion criteria were 25-75 years of age, unilateral or bilateral OA of the knee according to the American College of Rheumatology clinical criteria for the classification of idiopathic OA of the knee (i.e. knee pain plus at least three out of the following six: age >50 years, stiffness <30 min, crepitus, bony tenderness, bony enlargement, no palpable warmth), a total Western Ontario and McMaster Universities (WOMAC) osteoarthritis score of 15-75 (the worst score being 96) in the target knee, and ability to walk unassisted (may use walking stick, crutch or knee brace). Exclusion criteria were use on a regular basis of prescription drugs other than acetaminophen (paracetamol) to control pain, and use of oral or topical prescription or over-the-counter medications (other than acetaminophen), or of “natural” products for pain relief, 48 hours prior to randomisation or during the trial.

During the scientific evaluation, the Panel noted that the clinical tool used for the screening of the study subjects was designed to identify subjects with OA of the knee (Altman et al., 1986). EFSA highlighted to the applicant that the available scientific evidence does not establish that results obtained in patients with OA relating to the treatment of symptoms of this disease (e.g. erosion of articular cartilage, and reduced mobility of joints) can be extrapolated to the target population (subjects without the disease) for a claim on joint function (EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), 2012). In reply, the applicant argued that the lack of radiological confirmation of OA, and that acetaminophen was sufficient to control pain for the duration of the study could indicate that most of the subjects enrolled were healthy. The applicant also argued that even if the study population included some cases of OA, the results could be extrapolated to the target population for the claim because all subjects were able to live normal lives without medication.

The Panel notes that the study was specifically designed to identify patients with clinical diagnosis of OA rather than to exclude them, and considers that normal cells and tissues are genetically (gene expression) and functionally different from osteoarthritic cells and tissues, and therefore may respond differently to interventions with exogenous substances (FDA, 2004a,b). In addition, the mechanisms involved in the onset and/or progression of OA are largely unknown. It would have to be established, therefore, that an intervention which has an effect on the progression of the disease (in patients with OA) would also have an effect on its onset (subjects without the disease) (FDA, 2004a,b). The Panel

considers that no conclusions can be drawn from this study for the scientific substantiation of the claim.

The Panel notes that no studies from which conclusions could be drawn for the scientific substantiation of the claim were provided by the applicant.

The Panel concludes that a cause and effect relationship has not been established between the consumption of Cynatine[®] and maintenance of normal joint mobility.

CONCLUSIONS

On the basis of the data presented, the Panel concludes that:

- The food, Cynatine[®], which is the subject of the health claim, is sufficiently characterised.
- The claimed effect proposed by the applicant refers to “joint flexibility”. The target population proposed by the applicant is healthy adults, and in particular healthy individuals with “sensitive joints”. The health claim refers to the maintenance of joint mobility in subjects without chronic joint diseases, and does not include the treatment of chronic joint diseases. Maintenance of normal joint mobility is a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of Cynatine[®] and maintenance of normal joint mobility.

DOCUMENTATION PROVIDED TO EFSA

Health claim application on Cynatine[®] and maintenance of normal joint mobility pursuant to Article 13(5) of Regulation (EC) No 1924/2006 (Claim serial No: 0349_BE). May 2012. Submitted by Roxlor Nutra, LLC.

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- FDA (U.S. Food and Drug Administration), 2004a. Letter Regarding the Relationship Between the Consumption of Glucosamine and/or Chondroitin Sulfate and a Reduced Risk of: Osteoarthritis; Osteoarthritis related Joint pain, Joint Tenderness and Joint Swelling; Joint Degeneration; and Cartilage Deterioration (Docket No. 2004P-0059).
- FDA (U.S. Food and Drug Administration), 2004b. Letter Regarding the Relationship Between the Consumption of Crystalline Glucosamine Sulfate and a Reduced Risk of Osteoarthritis (Docket No. 2004P-0060).
- Wilson D and Veghte R, 2010 (unpublished, claimed as proprietary by the applicant). A randomized, double-blind, placebo controlled trial to investigate the effect of Cynatine FLX[™] on symptoms of osteoarthritis. KGK Study Code: 09POHR.

GLOSSARY/ABBREVIATIONS

OA Osteoarthritis

WOMAC Western Ontario and McMaster Universities